

REMARKS

A. Status of Claims

Favorable reconsideration of this Application, as presently amended, is respectfully requested. Claims 1, 5, 14, 23, 27, 30, 34, 40, 57 and 84-110 are currently pending.² Claims 1 and 97 are amended. Claims 2-4, 6-13, 15-22, 24-26, 28-29, 31-33, 35-39, 41-56 and 58-83 have been previously canceled. Claims 27, 30, 34 and 57 have been previously withdrawn. Claims 1, 5, 14, 23, 40, 57 and 84-110 are currently under consideration.

B. Support for the Amendments to Claim 97

Support for the above amendments to Claim 97 may be found in the specification at paragraphs [0040]³ and [0144] and in originally filed Claim 97, as well as elsewhere in the originally filed specification, drawings and claims.

C. Response to Rejection of Claim 97 under 35 U.S.C. § 112, Second Paragraph

At page 2 of the Office Action, Claim 97 is rejected under 35 U.S.C. §112, second paragraph as being indefinite.⁴ This rejection has been rendered moot by the above amendments to Claim 97.

D. Response to Rejection of Claims 1, 5, 14, 23, 40, 90, 91, 94, 96, 98, 100, 101, 104, 107, 109 and 110 under 35 U.S.C. § 103(a) as Being Unpatentable over Mathiowitz in View of Barach

At pages 2-5 of the Office Action, Claims 1, 5, 14, 23, 40, 90, 91, 94, 96, 98, 100, 101, 104, 107, 109 and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,985,354 to Mathiowitz et al. (hereafter “Mathiowitz”) in view of U.S. Pat. No. 4,720,460

² The Office Action Summary incorrectly does not list Claims 107-110 as currently pending.

³ All references to the specification are to U.S. Patent Application No. 2008/0102132 published May 1, 2008 (REPUBLICATION).

⁴ See Office Action, p. 2.

to Barach et al. (hereafter "**Barach**").⁵ This rejection is respectfully traversed for at least the following reasons.

Claims 1, 5, 14, 23, 40, 90, 91, 94, 96, 98, 100, 101, 104, 107, 109 and 110 each claim a continuous multi-microencapsulation process of biologically active materials that includes steps (b), (c), (d), (e) and (f) of Claim 1.⁶ In contrast, neither **Mathiowitz** and/or **Barach**, taken alone or in combination teach or suggest this combination of claimed features. Also, contrary to the requirements of 37 C.F.R. 1.104(c)(2),⁷ the Office Action has not cited where **Mathiowitz** and/or **Barach** teach or suggest these claimed features.

The claimed invention is used to form smaller microcapsules inside of large microcapsules as described, for example, in paragraph [0107] and shown in FIG. 7B. In contrast, **Mathiowitz** describes forming multilayer microcapsules⁸ as described, for example, at col. 2, lines 34-45; col. 3, lines 40-42; col. 5, line 64 to col. 6, line 6; col. 7, lines 26-30 and col. 10, lines 4-9 and in FIGS. 1 and 2 of **Mathiowitz**. FIG. 1 of **Mathiowitz** shows how a polymer A can engulf a polymer B⁹ to thereby form a multilayer microcapsules.¹⁰

In addition, **Mathiowitz** also does not teach step (b), step (c), step (d), step (e) or step (f) of the claimed invention and the Office Action has failed to cite any portion of **Mathiowitz** that teaches or suggests any of these steps. For example, **Mathiowitz** also does not teach or suggest and the Office Action has cited no portion of **Mathiowitz** that teaches or suggests step (b) of the claimed invention, i.e., adding a solution or dispersion in water that contains at least one hydrocolloid to the emulsion, "wherein the hydrocolloid is polymerizable due to the polymerization initiator, this producing a phase inversion and the cross-linking of the polymerizable hydrocolloid(s) onto the water in oil droplets." **Mathiowitz** also does not teach or suggest and the Office Action has cited no portion of **Mathiowitz** that teaches or suggests step (c) of the claimed invention, i.e., a step in which "a solution or dispersion in water that contains at least one protective colloid is added that begins to be deposited on the surface of the drops of

⁵ See Office Action, pp. 2-5.

⁶ Claim 1 explicitly claims these features. Claims 5, 14, 23, 40, 90, 91, 94, 96, 98, 100, 101, 104, 107, 109 and 110 depend from Claim 1, either directly or indirectly, and, therefore, also include these features.

⁷ 37 C.F.R. § 1.104(c)(2) states, in relevant part, that: "The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified" (emphasis added). See also MPEP § 707.05

⁸ Also referred to as "multiwall" microcapsules in **Mathiowitz**.

⁹ See **Mathiowitz** col. 7, lines 13-30

¹⁰ See **Mathiowitz**, col. 2, line 65 to col. 3, line 5.

water in oil, and to polymerize and cross-link with itself and the hydrocolloid.” **Mathiowitz** also does not teach or suggest and the Office Action has cited no portion of **Mathiowitz** that teaches or suggests step (d) of the claimed invention, i.e., a step in which “a solution or dispersion in water of a surfactant is added to allow a reduction of the size of the water in oil drops.” **Mathiowitz** also does not teach or suggest and the Office Action has cited no portion of **Mathiowitz** that teaches or suggests step (e) of the claimed invention, i.e., a step in which “during the process of reduction of size, the partially formed microcapsules are deagglomerated and reagglomerated, such that an enclosure of drops inside bigger drops eventually happens.” **Mathiowitz** also does not teach or suggest and the Office Action has cited no portion of **Mathiowitz** that teaches or suggests step (f) of the claimed invention, i.e., a step in which “when enough time has passed in order that the oil and/or water in oil drops are covered by at least one hydrocolloid and at least one protective colloid, the temperature is increased in order to strengthen the wall of the formed microcapsules or multi-microcapsules suspended in water.”

Also, nowhere does **Mathiowitz** teach or suggest a process, such as the process of the claimed invention wherein a water in oil emulsion is transformed through a series of steps into a water in oil in water structure/emulsion. Also, unlike in the claimed invention, **Mathiowitz** does not teach or suggest forming microcapsules and/or water droplets inside of microcapsules whose continuous phase is oil. In addition, **Mathiowitz** is silent with regard to the creation of a primary water in oil emulsion, and therefore the **Mathiowitz**’s process is essentially different from the process of the claimed invention.

Also, **Mathiowitz** does not teach or suggest the step producing the microcapsules as claimed in the present application, and **Mathiowitz**’s product does not yield the microcapsules of the claimed invention. In particular, there is no need to use the toxicant ethanol in the process of the claimed invention. In contrast the toxicant ethanol is necessary to obtaining a commercial product containing microcapsules described in **Mathiowitz**. Also, **Mathiowitz** does not teach or suggest possibility of using several hydrocolloids with several equally charged polymers as can be done with the claimed invention.

Furthermore, **Mathiowitz** is directed to a solvent evaporation process and uses evaporation as the driving force for the formation of microcapsules.¹¹ In contrast, the claimed invention is not a solvent evaporation process. **Mathiowitz** also does not teach or suggest the

¹¹ See, **Mathiowitz**, col. 2, lines 46-52 and Example 1, col. 11, lines 48-57.

claimed feature of forming a water in oil emulsion first that is later inverted to be an oil in water emulsion.

In Example 2, **Mathiowitz** uses complex coacervation, i.e., uses two oppositely charged polymers to form the microcapsules and then cools the microcapsules to 4 °C, a step not required in the claimed invention.

In general, **Mathiowitz** only describes methods of producing microcapsules of oil in a continuous medium that is water. Nowhere does **Mathiowitz** describe a process, such as the claimed invention in which some microcapsules contain water inside the oil inner phase and/or microcapsules fully formed inside other microcapsules. The claimed invention provides a process in which a water in oil emulsion is made and later is inverted to a water in oil in water emulsion resulting in multimicrocapsules. In contrast, **Mathiowitz** does not solve the problem of forming a water/oil/water emulsion at any stage in the process described in **Mathiowitz**.

Also, contrary to what is asserted in the Office Action, the differences between **Mathiowitz** and the claimed invention are not merely "order of the steps."¹² Also, the order of steps is an important feature of the claimed invention. For example, in the claimed invention, order of the steps is essential to obtain first a water in oil emulsion and then the final microcapsules' structure. For example, combining two water solutions to form a single water phase as described in Claim 1 of **Mathiowitz** is a completely different process than combining first a water phase with an oil phase, emulsify and then ONLY later, add a second water phase as is done in the claimed invention. The order of steps in **Mathiowitz** lead to a simple oil in water emulsion, a completely different result than in the process of the claimed invention .

For at least the above reasons, **Mathiowitz** cannot teach or suggest all of the features of Claims 1, 5, 14, 23, 40, 90, 91, 94, 96, 98, 100, 101, 104, 107, 109 and 110. Therefore, these claims are patentable over **Mathiowitz** for at least this reason.

Barach does not remedy the failure of **Mathiowitz** to teach or suggest all of the features of Claims 1, 5, 14, 23, 40, 90, 91, 94, 96, 98, 100, 101, 104, 107, 109 and 110. In particular, **Barach**, does not teach or suggest step (b), step (c), step (d), step (e) or step (f) of Claim 1.

Barach only describes a typical, simple mononucleous microencapsulation process. Nowhere does **Barach** teach or suggest a process wherein multimicrocapsules are formed. **Barach** refers exclusively to probiotic bacteria microencapsulation. Nowhere does **Barach**

¹² See Office Action, p. 4, last paragraph.

teach or suggest the claimed feature of a water in oil phase enclosed by the polymeric wall and suspended in water.

In addition, a person of ordinary skill in the art would have no reason to combine **Mathiowitz** with **Barach** in order to obtain the multilayered microcapsulated bacteria, much less the multimicrocapsules of the claimed invention) to protect bacteria. For example, in making its multilayered microcapsules, **Mathiowitz** describes using mineral oil at 80°C that would kill most bacteria.

For at least the above reasons, the combination of **Mathiowitz** in view of **Barach** cannot teach or suggest all of the features of Claims 1, 5, 14, 23, 40, 90, 91, 94, 96, 98, 100, 101, 104, 107, 109 and 110. Under 35 U.S.C. § 103, as stated at MPEP § 2143.03, “All words in a claim must be considered in judging the patentability of that claim against the prior art.”¹³ Therefore, because the combination of **Mathiowitz** in view of **Barach** cannot teach or suggest all of the features of Claims 1, 5, 14, 23, 40, 90, 91, 94, 96, 98, 100, 101, 104, 107, 109 and 110 for at least the reasons discussed above, the rejection of these claims under 35 U.S.C. § 103(a) as being unpatentable over **Mathiowitz** in view of **Barach** is *prima facie* improper and should be withdrawn.

E. Response to Rejection of Claims 1, 84-87 and 106 under 35 U.S.C. § 103(a) as Being Unpatentable over Mathiowitz in View of Unger

At pages 5-6 of the Office Action, Claims 1, 84-87 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mathiowitz** in view of U.S. Pat. No. 5,773,024 to Unger et al. (hereafter “**Unger**”).¹⁴ This rejection is respectfully traversed for at least the following reasons.

Claims 84-87 and 106 depend from Claim 1. Claim 1 is patentable over **Mathiowitz** for at least the reasons discussed above in Section D. **Unger** does not remedy the deficiencies of **Mathiowitz** in failing to teach or suggest all of the features of Claim 1.

Also, **Unger** is a document that a person of ordinary skill in the art would never consider when trying to obtain microcapsules described in **Mathiowitz**, because relates to liposomes.¹⁵ Therefore, **Unger** has have nothing to do with the structure of microcapsules with a hardened or

¹³ Citing *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) (emphasis added).

¹⁴ See Office Action, pp. 5-6.

¹⁵ See, for example, **Unger**, Summary of the Invention, col. 2, lines 35-48.

solidified wall. Furthermore, **Unger** describes enclosing gas, not liquids or solids.¹⁶ **Unger** does not even suggest that a liposome may contain inside a water in oil emulsion (surrounded by a wall) as happens in the microcapsules of the claimed invention.

For at least the above reasons, Claim 1 is patentable over the combination of **Mathiowitz** in view of **Unger**. Furthermore, because Claims 84-87 and 106 depend from Claim 1, Claims 84-87 and 106 are patentable over the combination of **Mathiowitz** in view of **Unger** for at least the same reasons that Claim 1 is patentable over this combination of references. Therefore, for at least the reasons discussed above, the rejection of Claims 1, 84-87 and 106 under 35 U.S.C. § 103(a) as being unpatentable over **Mathiowitz** in view of **Unger** is *prima facie* improper and should be withdrawn.

F. Response to Rejection of Claims 1, 88, 89, 102, 103, 105 and 108 under 35 U.S.C. § 103(a) as Being Unpatentable over Mathiowitz in View of Yan

At pages 6-7 of the Office Action, Claims 1, 88, 89, 102, 103, 105 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mathiowitz** in view of U.S. Patent Application No. 2003/0193102 to Yan et al. (hereafter "**Yan**").¹⁷ This rejection is respectfully traversed for at least the following reasons.

Claims 88, 89, 102, 103, 105 and 108 depend, either directly or indirectly from Claim 1. Claim 1 is patentable over **Mathiowitz** for at least the reasons discussed above in Section D. **Yan** does not remedy the deficiencies of **Mathiowitz** in failing to teach or suggest all of the features of Claim 1.

For at least the above reasons, Claim 1 is patentable over the combination of **Mathiowitz** in view of **Yan**. Furthermore, because Claims 88, 89, 102, 103, 105 and 108 depend from Claim 1, Claims 88, 89, 102, 103, 105 and 108 are patentable over the combination of **Mathiowitz** in view of **Yan** for at least the same reasons that Claim 1 is patentable over this combination of references. Therefore, for at least the reasons discussed above, the rejection of Claims 1, 88, 89, 102, 103, 105 and 108 under 35 U.S.C. § 103(a) as being unpatentable over **Mathiowitz** in view of **Yan** is *prima facie* improper and should be withdrawn.

¹⁶ See, for example, **Unger**, Summary of the Invention, col. 2, lines 35-48.

¹⁷ See Office Action, pp. 6-7.

CONCLUSION

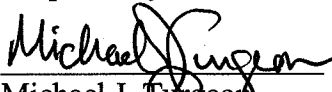
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this Application and the prompt allowance of all pending claims currently under consideration. Applicants also respectfully request that upon allowance of the claims currently under consideration, all currently pending claims that have been withdrawn and which depend from an allowed claim be reinstated and allowed. All pending claims that are not indicated as being withdrawn in the above Listing of Claims are believed by Applicants to read upon the elected species prosecuted in the present Application.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Mark J. Guttag at (202) 312-3381 to expedite prosecution of the Application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this Application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to **Deposit Account 22-0259**. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3) if needed.**

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